

US EPA ARCHIVE DOCUMENT

FEB 8 1990

## MEMORANDUM (CONFIDENTIAL)

SUBJECT: Product Chemistry Data Review for Technical Vinclozolin and Formulated Product Ronilan to Determine the Potential for Halogenated Dibenzo-p-Dioxin/Dibenzofuran Formation. I. D. No. 7969-53. Record No. 256251. MRID No. 40479701. DEB No. 6097

FROM: Stephen Funk, Chemist  
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Dietary Exposure Branch  
Health Effects Division (H7509C) *S Funk*

THRU: Andrew Rathman, Section Head  
Special Registration Section I  
Dietary Exposure Branch  
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TO: E. Feris, PM 74  
Special Review/  
Reregistration Division (H7508C)

Background

In response to a DCI of 06/09/87, BASF Corporation, Parsippany, NJ submitted (received 01/19/88) manufacturing data for technical 96% 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-1,3-oxazolidine-2,4-dione, or vinclozolin, and its formulated product, Ronilan Fungicide. The registrant claims CBI status for the information supplied. The purpose of the DCI is to acquire information on the potential for formation of halogenated dibenzo-p-dioxin or dibenzofuran contaminants during certain manufacturing processes. Three specific types of information were requested (Pesticide Assessment Guidelines, Subdivision D, Sections 61-1, 61-2, and 61-3):

1. Product identity and ingredients.
2. Description of beginning materials and manufacturing process.
3. Discussion of the formation of impurities.

VINCLOZOLIN

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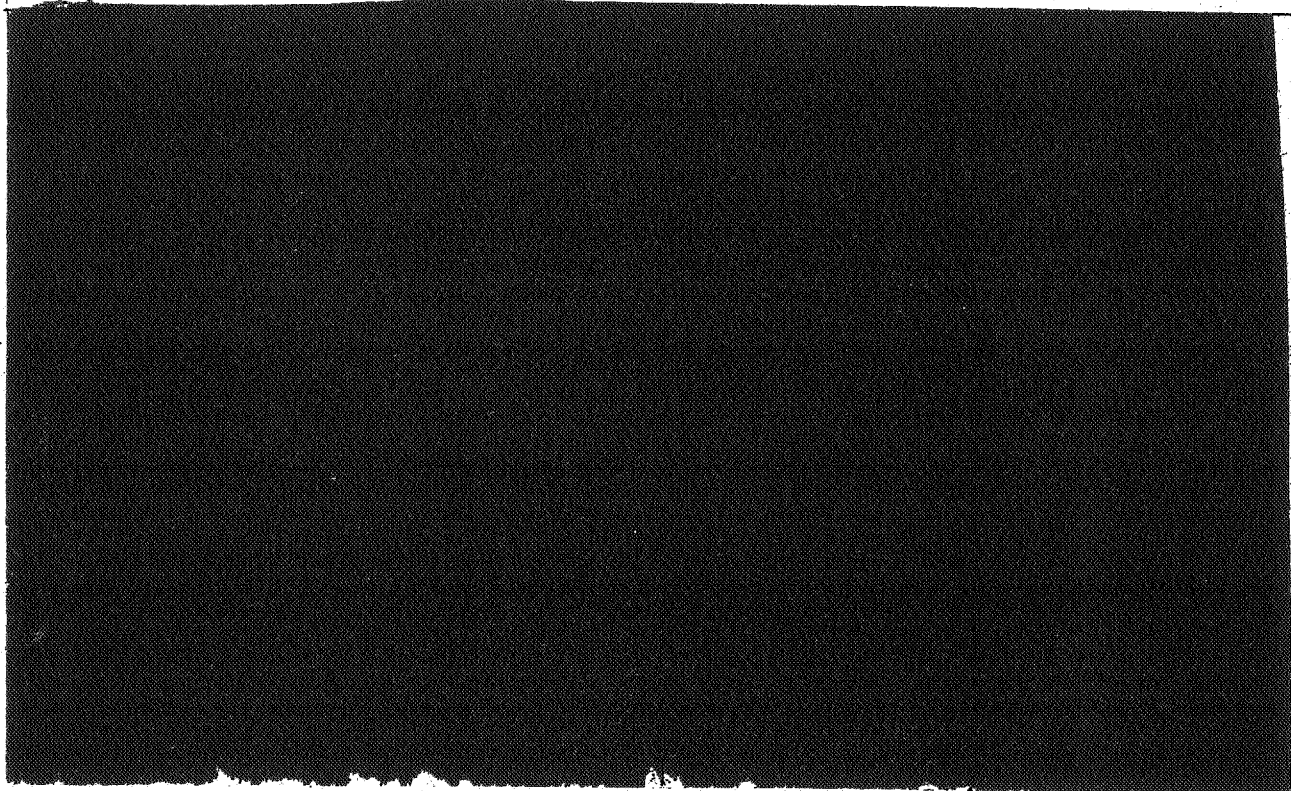
Pages 2 through 5 are not included.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☒ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) \_\_\_\_\_.
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED



Conclusion

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

The registrant has complied substantially with the DCI, but some manufacturing data were not supplied, specifically, reactor specifications, pressures, reaction times, pH, relative amounts of reactants, and details of product workup.

are difficult to explain based on the anticipated reactions and the reported impurities in the starting materials.

Nevertheless, vinclozolin, manufactured as described by BASF Corporation, will not contain halogenated dibenzo-p-dioxins/dibenzofurans. Dioxin precursors are not present in the starting materials, and reaction conditions in the synthesis are not appropriate for either precursor or dioxin synthesis. Alkalinity, available halogen, and temperatures above 145 degrees C (except step 1) are absent.

The formulated product Ronilan is made

particularly in view of the lack of any precursors.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Recommendation

DEB recommends that BASF Corporation not be requested to provide analytical chemistry data on halogenated dibenzo-p-dioxin/dibenzofuran contaminants in vinclozolin and formulated product Ronilan.

cc: Dioxin SF, RF, R. Schmitt (Branch Chief), Funk, Eldredge  
(PMSD, ISB).

RDI:A. Rathman:02/07/90:E. Zager:02/08/90:

H7509C:DEB:S. Funk:557-1439:CM#2:Rm803-A:SF (DIOX.21):01/18/90